IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

BRISTOL-MYERS SQUIBB & GILEAD SCIENCES, LLC, Plaintiff, v. LUPIN LIMITED, Defendant.	Civil Action No.: 2:14-cv-795

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Bristol-Myers Squibb & Gilead Sciences, LLC ("BMS & GS") for its complaint against Lupin Ltd. ("Lupin"), hereby alleges as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

The Parties

2. BMS & GS is a limited liability corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, defendant Lupin is an Indian corporation having its principal place of business at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

Jurisdiction and Venue

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, this Court has personal jurisdiction over Lupin.

6. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Texas and this District.

7. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in Texas and this District.

8. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, has sale representatives focused on the sale of pharmaceutical drug products in Texas and this District.

9. On information and belief, residents of the State of Texas purchase pharmaceutical drug products from Lupin in the State of Texas.

10. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, has authorized distributors in the State of Texas to distribute Lupin's pharmaceutical drug products throughout the State of Texas.

11. On information and belief, Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 20-5590, discussed below, indicates Lupin's intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with BMS & GS's Atripla® product, which is currently being sold throughout the United States,

including in Texas and this District. On information and belief, Lupin will sell the tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the use for which Lupin seeks approval in ANDA No. 20-5590, if approved, throughout the United States, including in Texas and this District.

12. On information and belief, Lupin has previously consented to personal jurisdiction in this District.

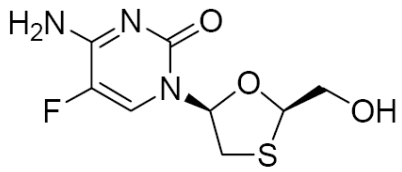
13. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Background

14. Gilead Sciences, Inc. is the holder of New Drug Application ("NDA") No. 21-937 which relates to tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-937 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Atripla®.

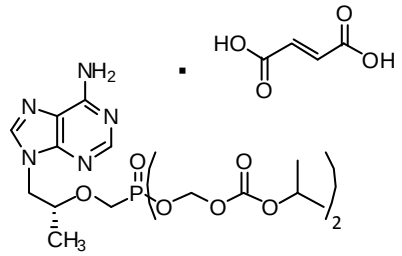
15. United States Patent No. 8,598,185 ("the '185 Patent," copy attached as Exhibit A), entitled "Unitary Pharmaceutical Dosage Form," was duly and legally issued by the United States Patent and Trademark Office on December 3, 2013. The '185 Patent claims, *inter alia*, a unitary dosage form containing tenofovir disoproxil fumarate and efavirenz in physically discrete compartments, and also containing emtricitabine. The '185 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Atripla®.

16. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:



17. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Atripla® label is "5-fluoro-1-(2*R*,5*S*)-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine."

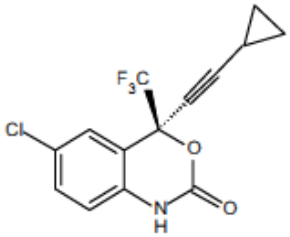
18. Tenofovir disoproxil fumarate is a compound that has a molecular formula of $C_{19}H_{30}N_5O_{10}P \cdot C_4H_4O_4$, and which has the following chemical structure:



TDF

19. Tenofovir disoproxil fumarate can be referred to by any of several chemical names. The chemical name given to tenofovir disoproxil fumarate in the Atripla® label is "9-[(*R*)-2[[bis[[(isopropoxycarbonyl)oxy]-methoxy]phosphinyl]methoxy]propyl]adenine fumarate (1:1)."

20. Efavirenz is a compound that has a molecular formula of $C_{14}H_9ClF_3NO_2$, and which has the following chemical structure:



21. Efavirenz can be referred to by any of several chemical names. The chemical name given to efavirenz in the Atripla® label is "(*S*)-6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-2H-3,l-benzoxazin-2-one."

22. The named inventors of the '185 Patent are Terrence C. Dahl, Munir A. Hussain, Robert A. Lipper, Robert L. Jerzewski, Mark M. Menning, Reza Oliyai, and Taiyin Yang.

23. Terrence C. Dahl, Munir A. Hussain, Robert A. Lipper, Robert L. Jerzewski, Mark M. Menning, Reza Oliyai, and Taiyin Yang assigned the '185 Patent to BMS & GS.

COUNT 1
Infringement of U.S. Patent No. 8,598,185

24. BMS & GS repeats and realleges paragraphs 1-23 above as if set forth herein.

25. On information and belief, Lupin submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-5590, to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

26. By letter dated June 13, 2014 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "June 13, 2014 Notice Letter"), Lupin notified BMS & GS that it had submitted ANDA No. 20-

5590 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '185 Patent.

27. In its June 13, 2014 Notice Letter, Lupin notified BMS & GS that, as a part of ANDA No. 20-5590, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '185 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '185 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

28. Lupin alleged in its June 13, 2014 Notice Letter that Claims 1-14 of the '185 Patent are both invalid and would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 20-5590.

29. The June 13, 2014 Notice Letter does not provide the full and detailed statement of Lupin's factual and legal basis to support its non-infringement and invalidity allegations as to the '185 Patent.

30. Accordingly, the June 13, 2014 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

31. By filing ANDA No. 20-5590 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate before the '185 Patent's expiration, Lupin has committed an act of infringement of the '185 Patent under 35 U.S.C. § 271(e)(2).

32. On information and belief, Lupin's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '185 Patent.

33. Lupin's submission of ANDA No. 20-5590 and service of the June 13, 2014 Notice Letter indicates a refusal to change its current course of action.

34. On information and belief, the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for which Lupin seeks approval in ANDA No. 20-5590, if approved, will infringe one or more claims of the '185 Patent.

35. The June 13, 2014 Notice Letter does not allege and does not address unenforceability of any claims of the '185 Patent. By not addressing unenforceability of any claims of the '185 Patent in its June 13, 2014 Notice Letter, Lupin admits that all of the claims of the '185 Patent are enforceable.

36. BMS & GS seeks a determination that this case is an exceptional one and an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, BMS & GS respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Lupin's ANDA No. 20-5590 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '185 Patent or any later date of exclusivity to which BMS & GS is or becomes entitled;

(b) A judgment declaring that the '185 Patent remains valid, enforceable, and that one or more claims have been infringed by Lupin;

(c) A permanent injunction against any infringement of the '185 Patent by Lupin, their officers, agents, attorneys, and employees, and those acting in privity or contract with them;

(d) A judgment that Lupin's conduct is exceptional in this case;

(e) An award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(f) To the extent that Lupin has committed any acts with respect to the subject matter claimed in the '185 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(g) Costs and expenses in this action; and

(r) Such other relief as this Court may deem proper.

July 24, 2014

Respectfully submitted,

/s/ David Bassett by permission Wesley Hill
David Bassett (Lead Attorney) (*pro hac vice forthcoming*)
David Manspeizer (*pro hac vice forthcoming*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Tel: 212-230-8800
Fax: 212-230-8888

Vinita Ferrera (*pro hac vice forthcoming*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: 617-526-6000
Fax: 617-526-5000

Nicholas M. Cannella (*pro hac vice forthcoming*)
Peter Shapiro (*pro hac vice forthcoming*)
Christopher P. Borello (*pro hac vice forthcoming*)
FITZPATRICK, CELLA, HARPER
& SCINTO
1290 Avenue of the Americas
New York, NY 10104
Tel: 212-218-2100
Fax: 212-218-2200

Colleen Tracy (*pro hac vice forthcoming*)
MAYER BROWN LLP
1675 Broadway
New York, NY 10019
Tel: 212-506-2122
Fax: 212-849-5336

T. John Ward
Texas State Bar No. 2084800
E-mail: tjw@wsfirm.com

J. Wesley Hill
Texas State Bar No. 24032294
E-mail: wh@wsfirm.com
WARD & SMITH LAW FIRM
1127 Judson Road, Ste. 220
Longview, Texas 75601
Tel: 903-757-6400
Fax: 903-757-2323

Attorneys for Plaintiff Bristol-Myers Squibb & Gilead Sciences, LLC